REMARKS

The present application is directed to a method and kit for detecting animal byproducts in samples. The method and kit are particularly useful in the detection of animal byproducts in feed, such as animal byproducts rendered in meat and bone meal. Detection of animal byproducts in feed is useful for reducing transmission of pathogens such as those causing mad cow disease.

Following entry of this amendment, Claims 1-8, 10-11, 13-15 and 17-18 will be pending. Claim 14 is withdrawn, and Claims 9, 12, 16 and 19-22 are cancelled. Claim 1 is currently amended. No new matter is added and support for the amendments is found throughout the specification and in the original claims.

Claim rejections 35 U.S.C. §112, first paragraph

In the Office Action mailed January 4, 2006, the Examiner rejected Claims 1-8, 10, 11, 13, 15, 17 and 19-21 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 1 is amended herein to recite "...wherein the amount of rendered animal byproduct detected by the method is about 0.005% to about **0.01%**." Applicants respectfully submit that this range is disclosed on page 21, lines 20-22 of the instant application. Accordingly, Applicants respectfully submit they have overcome the rejection under 35 U.S.C. §112, first paragraph and request its withdrawal.

Claim rejections 35 U.S.C. §102 (a)

In the Office Action mailed January 4, 2006, the Examiner rejected Claims 1, 8, 13 and 22 under 35 U.S.C. §102(a), as anticipated by Chen *et al.* (*Meat Science* 2002) (hereinafter "Chen *et al*"). Applicants respectfully submit that the amendments to the claims overcome the rejection.

As mentioned above, amended Claim 1 recites that the amount of rendered animal byproduct detected is about 0.005% to about **0.01%** by weight of the animal feed sample.

Chen *et al.* disclose the use of an indirect ELISA immunoassay to detect rendered muscle in animal feedstuff with a detection limit between 0.3 and 2%. While Chen *et al.* infer that one might lower the detection limit by employing a sandwich assay to about 0.1%, Chen *et al.* fail to teach one of ordinary skill in the art how to achieve a highly sensitive detection limit of 0.01% as claimed by applicants.

Therefore, Applicants respectfully submit that the claimed method is novel over Chen *et al.* and request withdrawal of the rejection under 35 U.S.C. §102(a).

Claim rejections 35 U.S.C. §102 (e)

In the Office Action mailed January 4, 2006, the Examiner rejected Claims 1, 8, 13 and 22 under 35 U.S.C. §102(e), as anticipated by Hsieh *et al.* (US 2003/0022248 hereinafter "Hsieh *et al*"). Applicants respectfully submit that the amendments to the claims overcome the rejection.

Hsieh *et al.* disclose the use of an indirect ELISA immunoassay to detect rendered muscle in animal feedstuff with a detection limit between 0.3 and 2%. Hsieh *et al.* infer that this detection limit might be lowered to 0.1% by utilizing their antibodies in a sandwich assay format. This detection limit remains ten-fold higher than that claimed in the instant invention. There are no disclosed embodiments that teach or suggest that one could lower the detection limit substantially below 0.1% with a reasonable expectation of success.

In view of the higher sensitivity of the claimed method, Applicants respectfully submit that the claimed method is novel over Hsieh *et al.* and request withdrawal of the rejection under 35 U.S.C. §102(e).

Claim rejections 35 U.S.C. §103 (a)

In the Office Action, the Examiner rejected Claims 2 and 17 under 35 U.S.C. §103(a) as unpatentable over Voller (The Enzyme linked Immunosorbent Assay, *Diagnostic Horizons*, vol 2, no.1, 1978; hereinafter "Voller") in view of Hsieh *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.01% by weight. Voller discloses and ELISA assay wherein an antibody bound to a solid surface captures the analyte and a second enzyme labeled antibody detects the bound analyte. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Voller because Voller also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight.

Accordingly, Applicants respectfully submit that the detection limits of the pending claims would not have been obvious to one skilled in the art at the time of the invention in view of the teachings of Voller and Hsieh *et al.* and request withdrawal of the Examiner's rejection under 35 U.S.C. §103(a).

The Examiner rejected Claim 3 under 35 U.S.C. §103(a) as unpatentable over Hsieh *et al.* in view of U.S. Patent No. 3,654,090 to Schuurs *et al.* and further in view of U.S. Patent No. 5,437,981 to Deger *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 3 depends from amended Claim 1 and contains all the limitations thereof. Claim 3 further specifies that the sample is combined with both the ligand (having a detectable label) and an analyte analog that is bound to a solid phase, and that the detectable ligand has a binding affinity for the analyte analog.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005% to about 0.01% by weight. Schuurs *et al.* disclose a test system composed of an antigen, labeled antibody and insolubilized antigen, wherein the amount of soluble antigen can be measured from the distribution of labeled antibody over the liquid and solid phases. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Schuurs *et al.* because Schuurs *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight. Deger *et al.* disclose a competitive immunoassay utilizing an immobilized analogue of the analyte of interest. The amount of analyte in the sample is determined by the distribution of a labeled antibody between the liquid and solid phases. The deficiencies of Hseih *et al.* and Schuurs *et al.* are not satisfied by the teaching of Deger *et al.* because Deger *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005% to about 0.01% by weight.

The Examiner rejected Claim 4 under 35 U.S.C. §103(a) as unpatentable over Hsieh *et al.* in view of U.S. Patent No. 5,571,682 to Jacobs *et al.* and U.S. Patent No. 6,617,116 to Guan *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 4 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 4 specifies that the sample is combined with both the ligand and a detectable analyte analog, and that the ligand is bound to a solid phase and has binding affinity for the detectable analyte analog.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about

0.005 % to about 0.01% by weight. Jacobs *et al.* discloses an competitive immunoassay wherein the analyte of interests competes with a labeled analyte analog for binding to an immobilized antibody. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Jacobs *et al.* because Jacobs *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight. Guan *et al.* disclose a competitive immunoassay wherein an analyte of interest competes with a labeled analog analyte for binding to an immobilized binding partner. The deficiencies of Hseih *et al.* and Jacobs *et al.* are not satisfied by the teaching of Guan *et al.* because Guan *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005% to about 0.01% by weight.

The Examiner rejected Claims 5 and 6 under 35 U.S.C. §103(a) as unpatentable over Hsieh *et al.* in view of U.S. Patent No. 5,910,446 to Ansfield. Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 5 and 6 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 5 specifies that the amounts of bound complex can be determined using the method of Claim 1. Claim 6 specifies that the analyte is a component of meat and bone meal.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.01% by weight. Ansfield provides a preparative method for concentrating heat stable proteins in order to increase the sensitivity of tests such as immunoassays that incorporate this method as a preliminary step. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Ansfield because Ansfield also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight.

The Examiner rejected Claims 7 and 10 under 35 U.S.C. §103(a) as unpatentable over Hseih *et al.* in view of U.S. Patent Application No. 2003/0083255 to Thorn *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claims 7 and 10 depends from amended Claim 1 and contains all the limitations thereof. In addition, Claim 7 specifies that the analyte is a component of rendered connective tissue or bone. Claim 10 specifies that the analyte is a component of the extracellular matrix of bone or cartilage.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.01% by weight. Thorn *et al.* discloses that Troponin I is a component of connective tissue. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Thorn *et al.* because Thorn *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight.

The Examiner rejected Claim 11 under 35 U.S.C. §103(a) as unpatentable over Hseih *et al.* in view of U.S. Patent No. 6,022,694 to Radziejewski *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 11 depends from amended Claim 1 and contains all the limitations thereof. In addition claim 11 specifies that the analyte is chondroitin sulfate, aggrecan, osteocalcin, hyaluronic acid, or Type II collagen.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.01% by weight. Radziejewski *et al.* discloses assays for detecting Type

II collagen in a sample. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Radziejewski *et al.* because Radziejewski *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight.

The Examiner rejected Claims 15 and 18-21 under 35 U.S.C. §103(a) as unpatentable over Hseih *et al.* in view of U.S. Patent No. 4,444,879 to Foster *et al.* Applicants respectfully submit that the amendments to the claims overcome the rejection.

Claim 15 specifies a kit for performing the method of Claim 1. Claim 18 specifies that the amount of rendered animal byproduct detected is about 0.005% to about 0.01% by weight. Claims 19-21 have been canceled without prejudice.

As mentioned above with regard to the rejections under 35 U.S.C. §102(e) Hsieh *et al.* fails to teach or suggest a high sensitivity method for detecting rendered animal byproduct in a sample, wherein the amount of rendered animal byproduct detected is about 0.005 % to about 0.01% by weight. Foster *et al.* discloses a solid-phase support for immobilizing reactants of an immunoreaction and methods for manufacture and use of the support of the invention in an immunoassay for proteins. The deficiencies of Hsieh *et al.* are not satisfied by the teachings of Foster *et al.* because Foster *et al.* also fails to teach or suggest a method for detecting rendered animal byproducts in a sample, wherein the amount of rendered animal byproduct is about 0.005 % to about 0.01% by weight.

Therefore, for at least the foregoing reasons, applicants respectfully submit they have traversed or overcome the rejections under 35 U.S.C. §103(a) and request withdrawal thereof.

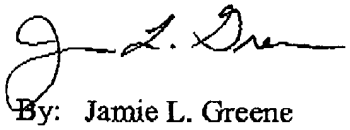
CONCLUSION

Applicants respectfully submit this is a complete response to the Final Office Action dated January 4, 2006, and that the pending claims are definite, novel and non-obvious. Accordingly, Applicants respectfully request allowance of these claims.

No additional fees are believed due, however, the Commissioner is hereby authorized to charge any deficiencies that may be required or credit any overpayment to Deposit Account Number 11-0855.

Early and favorable consideration is earnestly solicited. If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application that may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney at (404) 815-6500 is respectfully solicited.

Respectfully submitted,



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